

JUL 23 2004

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Noble Fiber Technologies, Inc.

510(k) Premarket Notification  
X-Static® Silverseal™ Hydrogel Wound Dressing

July 12, 2004

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10. 510(k) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Noble Fiber Technology, Inc.  
421 South State Street  
Clarks Summit, PA 18411

Contact Person and telephone number:

William McNally, President  
Telephone: 877-978-2842  
Telefax: 877-978-2842

Date Summary was Prepared

December 31, 2003

10.1.2 Name of Device

Trade Name:	X-Static® SILVERSEAL™ Hydrogel Wound Dressing
Common Name:	Silver-nylon Hydrogel Wound Dressing
Classification Name:	Hydrogel Wound Dressing

10.1.3 Identification of predicate device to which substantial  
equivalence is being claimed

X-Static® SILVERSEAL™ Hydrogel Wound Dressing is a flexible, non-adherent, protective dressing consisting of hydrogel (water-based), and nylon fibers with a metallic silver surface. \*It is substantially equivalent to phytacare Alginate Hydrogel Wound Dressing (K980132, PhytaTek Laboratories, Inc.), BurnFree Sterile Burn & Wound Dressing (K010583, Ambu, Inc.), Collatek Hydrogel Dressing (K022995, BioCare Medical Technology, Inc.), Woun'Dres Hydrogel Dressing (K991202, Coloplast Corp.), Nu-Gel Wound Dressing, (K983362, Johnson & Johnson), DuoDerm Hydroactive Gel Dressing, (K990368, Convatec, Div. Of E.R. Squibb & Sons, Inc.), Acryderm Silver Antimicrobial Wound Gel #A, (K011994, Acrymed, Inc.), Acticoat Composite Dressing (K002466, Westaim Biomedical, Inc.)

10.1.4 Device Description

Explanation of how the device functions: X-Static® SILVERSEAL™ Hydrogel Wound Dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination.

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\*Basic scientific concepts that form the basis for the device:  
The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in X-Static® SILVERSEAL™ Hydrogel Wound Dressing consists of a thin layer of metallic silver containing approximately 1.5% silver oxide that provides effective protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: X-Static® SILVERSEAL™ Hydrogel Wound Dressings are made of flexible, sterile, non-adherent fabric consisting of 1 layer of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately 1% silver oxide.

**10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended**

The X-Static® Silverseal™ Hydrogel Wound Dressing is intended for the management of wounds and to provide an antimicrobial barrier. The dressing is indicated for use on partial and full thickness dermal ulcers, leg ulcers, superficial wounds, abrasions, first and second degree burns, donor sites and over debrided and grafted partial thickness wounds.

**10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device**

The technological characteristics of the device, such as flexible primary Hydrogel Wound Dressing, permeability to oxygen and fluids, and protection against microbial contamination of the dressing that are substantially equivalent to the predicate devices cited.

**10.2 Assessment of Performance Data**

X-Static® SILVERSEAL™ Hydrogel Wound Dressings were subjected to standard tests including cytotoxicity, sensitization, and acute intracutaneous reactivity. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North American Science Associates, Inc. (NAMSA). All antibiotic claims are the result of *In Vitro* studies and that the effect of the antibiotic has not been studied in a clinical setting. The studies indicated that X-Static® SILVERSEAL™ Hydrogel Wound Dressings are safe for their intended use.

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\* Represents Confidential or Trade Secret Information and the protection afforded to such confidential information by 18 U.S.C. §1905, 21 U.S.C. §331(j), 5 U.S.C. §552, and other applicable laws is hereby claimed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 23 2004

Mr. William McNally  
President  
Noble Fiber Technology, Inc.  
421 South State Street  
Clarks Summit, Pennsylvania 18411

Re: K040019  
Trade/Device Name: X-Static® SilverSeal™ Hydrogel Wound Dressing  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: June 15, 2004  
Received: June 16, 2004

Dear Mr. McNally:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

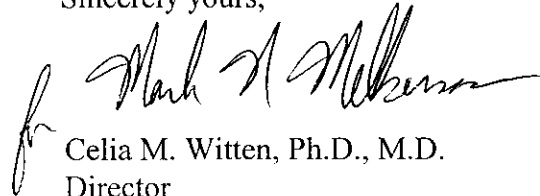
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. William McNally

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040019

Device Name Silverseal Hydrogel Dressing

Indications For Use: The X-Static® Silverseal™ Hydrogel Wound Dressing is intended for the management of wounds and to provide an antimicrobial barrier. The dressing is indicated for use on partial and full thickness dermal ulcers, leg ulcers, superficial wounds, abrasions, first and second degree burns, donor sites and over debrided and grafted partial thickness wounds.

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

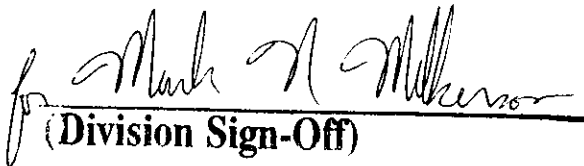
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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